CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8

> Our Case No. 8627-1391 Client Ref. No. PA-5511-PCT/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
David G. Burton et al.))
Serial No.: 10/593,376	Examiner: Sarah K. Webb
Filing Date: July 9, 2007	Group Art Unit No.: 3734
For: MEDICAL BALLOON WITH ENLARGED TRANSITIONAL RADII	, Confirmation No.: 8852

SECOND DECLARATION OF DAVID G. BURTON

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

Now comes David G. Burton, who declares and states:

- I live at 6524 E. Everett Arnold Dr., Bloomington, IN 47408. I have been employed by Cook Inc. for 12 years, and have been responsible for product development during my employment with Cook Inc. I am currently employed by Cook Inc. as a Sr. Engineer and work as part of the balloons and stents team. I am one of the named inventors of the above-identified patent application.
- 2. It is my understanding that the Examiner has rejected the claims of the above-identified application because the Examiner argues that the numerical values in the claims and the specification do not indicate whether they relate to a deflated balloon or an inflated balloon. Based on my review of the application, and my personal experience, I offer the following opinions on how one of ordinary skill in the art would understand the claims.

- 3. As explained in paragraph [0036] of the application, the enlarged radii described in the specification and claimed in the claims may be measured when the medical balloon is unfolded. One of ordinary skill in the art understands that in order to thread a medical balloon through an artery, it must be deflated and then wrapped around itself to form a small diameter profile. A description of this is provided in the background section in paragraph [0008]. Thus, the reference to measuring the radii in the unfolded state clearly refers to the deflated state before the balloon has been folded for insertion through an artery. This is also described in paragraph [0047] where a conventional balloon 1300 is compared before inflation (Figure 13A) and after inflation (Figure 13B) to an enlarged radii balloon 1350 before inflation (Figure 13C) and after inflation (Figure 13D). Thus, one of ordinary skill in the art would understand the references in the specification and the claims to transition radii to refer to radii before the balloon is inflated
- As described in paragraphs [0002]-[0005] and recited in the claims, the inventions of the application relate to a dilation catheter. As described in the background section of the specification, dilation catheters are used to apply pressure against the interior of a biological conduit. One of ordinary skill in the art understands that these types of catheters use an inelastic balloon in order to withstand very high pressures without uncontrollably expanding to an unpredictable diameter. As a result, the diameter of a medical balloon on a dilation catheter is substantially the same both in the deflated state and the inflated state. This is illustrated graphically in Figures 13A-D. where Figures 13A and 13C are shown before inflation and Figures 13B and 13D are shown after inflation. As shown, the diameter of the balloons does not change significantly from the deflated state to the inflated state. As explained, this is important so that the physician using the dilation catheter will know beforehand what diameter the balloon will expand to regardless of the pressure applied to the balloon. Thus, one of ordinary skill in the art would understand the references in the specification and the claims to balloon diameters to refer to a balloon having the specified diameter both in the deflated and inflated states.
- I state that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further

that these statements were made with knowledge that willful false statements are the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

David G. Burton